

**Comments by the American Society for Biochemistry and Molecular Biology to the
Energy and Commerce Committee
Request for Comments on “21st Century Cures Act” Discussion Draft
February 10, 2015**

We applaud the work of the U.S. House Energy and Commerce committee on the 21st Century Cures initiative. The ASBMB has been involved in the conversation surrounding this initiative as we commented on two previous white papers from the committee, and we appreciate the opportunity to comment on this discussion draft. We look forward to being a part of this process as it moves forward.

Our members are basic researchers funded primarily by the National Institutes of Health. Thus, we have restricted our comments to the sections that would most affect our members. Sections not discussed here should not be construed as support of those sections.

Sec. 2001 – Innovative Cures Consortium

Our concern: This section would establish a nonprofit organization that issues grants to organizations for speeding the development and delivery of lab discoveries. However, the granting activity of this NPO is set up to run almost exactly like the largely successful STTR program. The proposed NPO and the STTR program grant money to small companies and nonprofit organizations. And both require the organization receiving the grant to commit its own resources to the funded project. Furthermore, those eligible for funding from this new NPO would be the same population as those eligible for NIH STTR support.

Our recommendation: To avoid a duplication of efforts and increasing bureaucracy, we suggest replacing the language creating this new NPO and rewriting the section to authorize money specifically for the NIH STTR program. Alternatively, should the NPO remain in the legislation, we encourage the committee to include language that would clearly delineate the roles of this NPO relative to STTR programs.

Sec. 2241 – Plan for longitudinal study on outcomes of patients with a chronic disease

Our concern: This section directs the NIH to identify a chronic illness, report on the state of research on that disease and design and execute a longitudinal study of that disease with the goal of generating new treatments and cures for that disease. However, dictating that the NIH or other agencies pick one of subset of diseases to build a research repertoire around damages research into other diseases. Furthermore, the dedicated research program has no guarantee of success. Research works best when scientists are competing for grants that are awarded based on exemplary, peer-reviewed grant applications. Congressionally directed research into a disease, even with as vague of a directive stated here, is a gamble of taxpayer dollars that are better spent supporting investigator-initiated research.

Our recommendation: Rewrite this section to have the NIH report on all long-term studies of chronic diseases omitting any plan for a long-term research project. Congress should then work with the scientific community and the NIH to find ways to incentivize research into understudied diseases.

Sec. 2261 – Funding research by emerging scientists through Common Fund

Our concern: This section would stop the transfer of money from NIH to AHRQ through what is commonly called “the tap.” The money saved by the NIH would be directed to funding “emerging scientists.” We have several concerns with this section.

- (1) The diversion of money from AHRQ damages the research community as a whole. All research is interconnected. AHRQ ensures that the discoveries made by NIH-funded researchers that turn into FDA-approved products are delivered and being used in the most effective and efficient ways possible. This type of research is critical for the NIH, CDC and FDA to improve on these products and ensure that they are available to all who need them. Furthermore, the goal of the 21st Century Cures initiative is to improve not only the path from discovery through development and delivery, but also to improve how patient feedback affects research and discovery.¹ The work of AHRQ is critical for this second part. It is not clear how the 21st Century Cures initiative benefits from potentially reducing the effectiveness of AHRQ.
- (2) On p.219, line 1, the definition of an “emerging scientist” differs substantially from the NIH’s definition of an Early Stage Investigator. Introducing a new class of investigator on top of a very similar class will cause confusion in the community and lead to inefficiencies in grant awarding and data analysis.
- (3) It is not clear why money is being diverted to “emerging scientists” in the manner indicated here. (1) The NIH policy of ensuring Early Stage Investigators have a fair shot at receiving grant money has been largely successful—grant applications from ESIs have nearly the same chance of success as established investigators.² (2) It is generally assumed that Early Stage Investigators have a difficult time securing their second NIH grant. If helping scientists secure their second grant is the point of this section, the legislation should be rewritten to clearly address this.

Our recommendation: The following section, Sec. 2262, requires the NIH to report on aging trends in the biomedical workforce. This report should be completed before any legislative attempts are made at funding specific constituencies within the workforce. Doing so may only introduce more problems. Furthermore, we feel the goals and funding mechanism of this section are misguided. As such, we recommend Sec. 2261 be removed from the final legislation. If this section remains, then we recommend:

- (1) If the goal of turning off the tap is to give the NIH more money, we recommend instead authorizing and appropriating more money for the NIH.
- (2) The legislation should conform to preexisting definitions of Early-Stage Investigators at the NIH and drop the “emerging scientist” nomenclature. On the other hand, if the point of (b)(2) is to make it easier for young scientists to win their second major award from the NIH, then the legislation should be clarified and written specifically toward that population of scientists. Furthermore, data on these scientists should be included in the report specified in Sec. 2262.

Sec. 2262 – Report on trends in age of recipients of NIH-funded major research grants

We support the analysis of aging trends in NIH-funded researchers

Our recommendation: We have two recommendations: (1) We suggest language be included directing the NIH to also report on the Early Stage Investigator program and how scientists typically fare transitioning out of this program. (2) We suggest that the reports in this section be made prior to legislating significant changes to the biomedical workforce as in Sec. 2261.

¹ <http://energycommerce.house.gov/cures>

² <http://report.nih.gov/nihdatabook/index.aspx>. “R01-Equivalent grants, New (Type 1): Success rates, by career stage of investigator”

Sec. 2281 – High-risk, high-reward research program

Our concern: This section directs all NIH institutes and centers to reserve money for high-risk, high-reward research. Forcing institutes and centers to fund this type of research, which is already done well by the Common Fund, will divert funding from other well established programs that fund many researchers doing excellent work. Furthermore, high-risk, high-reward research is often transdisciplinary. One of the reasons the Common Fund was created was to fund high-risk, high-reward, transdisciplinary research.

Our recommendation: To expand high-risk, high-reward research at the NIH, the legislation should be rewritten to authorize an increase to this type of research through the Common Fund. This should be a redistribution of funds within the Common Fund, as we do not support Sec. 4007, which would authorize more money for the Common Fund. In an otherwise stagnant budget environment, increasing overall funding for the Common Fund would negatively affect researchers funded by other NIH mechanisms.

Sec. 4001 – NIH research strategic investment plan

Our concern: This section directs the NIH to develop a strategic investment plan. We support the idea that the NIH should have a long-term plan for how its appropriations will be invested. However, we are concerned about the 10 Mission Priority Focus Areas described on p.243, line 7. The scientific research enterprise works at its best when undirected, investigator-initiated research is fully funded. We understand the urge to direct funds into a specific disease or area of research. However, funding initiatives in this manner is not a guarantee of success or even progress. Rather, the American biomedical research program should continue to be funded as it has in the past—by valuing the contributions of investigator-initiated research and relying on projects proposed by scientific experts.

Our recommendation: The language regarding the Mission Priority Focus Areas should be removed.

Sec. 4002 – Biomedical research working group to reduce administrative burden on researchers

We support work to relieve the administrative burden on researchers.

Our recommendation: In the 113th Congress, H.R.5056, which would have established an inter-agency working group to address administrative burden at all federal science funding agencies, passed the U.S. House. We recommend placing a provision in the 21st Century Cures Act that, should legislation similar to H.R.5056 create a government-wide working group on administrative burden at science funding agencies, the NIH-specific administrative burden working group specified in this bill be disbanded, and their work handed over to the government-wide working group.

Sec. 4003 – NIH travel

Our concern: Attending research conferences is an essential part of being a part of the scientific community. These events are not boondoggles, but rather these conferences provide forums for improving training, sharing results and ideas, and forming collaborations.

Our recommendation: NIH scientists should be able to travel to scientific conferences without restriction in order to appropriately contribute to the American scientific enterprise.

Sec. 4004 – Increasing accountability at the National Institutes of Health

Our concern: This section seeks to improve accountability at the NIH. However, the provisions in this section would not achieve this and would only add to bureaucratic processes that slow discovery research. Specifically,

- (1) Sec. 4004(b), p.251, line 7 would require institute and center directors to personally review and approve all awards. NIH-funded grants undergo rigorous peer review by eminent scientists in the field as well as evaluation by the institute's council. Adding another layer of review by the institute director is unnecessary given these two prior rounds of rigorous review. Furthermore, the time and effort required by a director to fulfill this directive would cripple his/her ability to direct the activities of the institute and significantly slow the groundbreaking research sought by the 21st Century Cures initiative.
- (2) Sec. 4004(b), p.251, line 10 requires that NIH-funded grants have goals that are of "a national priority and have public support." Biomedical research and its fruits are a national priority and this research enjoys widespread public support.³ Asking this metric to be true on a grant-by-grant basis would require polling the public on which specific grant applications should be funded. This is not possible given the budget of the NIH, the time the director would have to spend ascertaining this information, and the scientific capabilities of the general public.
- (3) Sec. 4004(b), p.251, line 13 would ask institute directors to ensure that other agencies are not funding work that accomplish the same goal. Scientific results must be verifiable and reproducible in labs other than the one making the initial discovery. Scientists conducting research all trying to achieve the same goal is how we make sure that the scientific answers that are found are correct. Preventing multiple researchers from pursuing the same scientific goals is antithetical to research and the spirit of what the 21st Century Cures initiative is trying to attain.
- (4) Sec. 4004(b), p.251, line 16 requires institute directors to assess the money invested in a grant relative to the potential scientific discovery. Basic, discovery research is so named because no one knows the results of the experiment they are about to conduct. Furthermore, the potential scientific discovery may lead to other discoveries and developments years or decades in the future. It is not possible for anyone to accurately predict the outcomes of discovery research much less determine whether the financial investment is worthwhile given the long timeframes required for some discoveries to be used.
- (5) Sec. 4004(c) and (d) request the GAO to study waste, fraud and lack of consistency at the NIH as well as duplication in biomedical research. We support improving efficiencies at all federal agencies including the NIH. These studies should be completed before any legislative attempts are made to improve accountability at the NIH.

Our recommendation: Sec. 4004(b) should be removed in its entirety. We support Sec. 4004(c) and (d).

Sec. 4007 – Additional funding for NIH Common Fund

Our concern: This section authorizes more funding for the Common Fund. Without an increase to the overall NIH budget and concomitant increases to the budgets of all institutes and centers, a boost in the budget of the Common Fund will mean a reduction in the funding for other institutes and centers. This will mean that important investigator-initiated research will not be funded. Given the stagnant federal budget for research over the past ten years, reducing funding to any part of the NIH will harm research.

Our recommendation: Remove Sec. 4007.

³ Research!America. "America Speaks" vol. 14. <http://www.researchamerica.org/uploads/AmericaSpeaksV14.pdf>.



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Sec. 4008 – Additional funding for NIH brain research

Our concern: This section authorizes more funding for the BRAIN initiative. The scientific research enterprise works at its best when undirected, investigator-initiated research is fully funded. Diverting resources to specified projects, such as the BRAIN initiative, detracts from the vibrance and productivity of the enterprise. We prefer a system where scientists compete for grants that are awarded based on exemplary, peer-reviewed grant applications.

Our recommendation: Remove Sec. 4008.